

K081533

JUN 25 2008

510(k) Summary

Submitter's Name/Address

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Date of Preparation of this Summary:

May 30th, 2008

Device Trade or Proprietary Name:

Sentinel Plasmaproteins Cal 3X

Device Common/Usual Name or

Classification Name:

Plasmaproteins Cal 3X

Classification Number/Class:

JIX/Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

Device Description:Original (Plasmaproteins Cal 3x, K051457).

The Sentinel Plasmaproteins Cal 3x is a liquid, ready-to-use calibrator prepared from plasmatic plasmaproteins in human-based serum. It consists of 4 x 1 mL bottles of aqueous material containing Ceruloplasmin, Kappa light chains and Lambda light chains in a human serum matrix. This material, when stored as directed, is stable until the date printed on the label. Calibrator traceability was stated as certificated to CRM 470 (Certified Reference Material).

Modified Plasmaproteins Cal 3x

The Sentinel Plasmaproteins Cal 3x is a liquid, ready-to-use calibrator prepared from plasmatic plasmaproteins in human-based serum. It consists of 4 x 1 mL bottles of aqueous material containing Ceruloplasmin, Kappa light chains, Lambda light chains, Transferrin, Alpha 1-Acid Glycoprotein, Alpha 1-Antitrypsin, Haptoglobin, Immunoglobulin A, Immunoglobulin G and Immunoglobulin M in a human serum matrix. This material, when stored as directed, is stable until the date printed on the label. Calibrator traceability was stated as certificated to CRM 470 (Certified Reference Material), renamed ERM-DA 470 (European Reference Materials).

Description of modifications:

The modified Plasmaproteins Cal 3x is substantially equivalent to the previous cleared Sentinel Plasmaproteins 3x (K051457) and to the predicate device Roche Calibrator for Automated Systems (C.f.a.s.) Proteins (K011226).

The modification with respect to K051457 consists of certification in the following new analytes:

- a) Alpha 1-Acid Glycoprotein
- b) Alpha 1-Antitrypsin
- c) Haptoglobin
- d) Immunoglobulin A
- e) Immunoglobulin G
- f) Immunoglobulin M
- g) Transferrin

All the above listed analytes are already contained in the original Plasmaproteins Cal 3x. Thus neither modification of the chemical's compositions nor of its production procedures have been made to the original Plasmaproteins Cal 3x (K051457).

These modifications did not significantly change the safety and effectiveness of the device as demonstrated in the Performance Characteristics Summary.

Intended Use:

Sentinel Plasmaproteins Cal 3x must only be used for the calibration of plasmaprotein tests with the immunoturbidimetric methods.

Description of the Calibrator Material:

Sentinel Plasmaproteins Cal 3x contains analytes (plasmaproteins) in human serum based matrix. The analytes consist of:

- a) Alpha 1-Acid Glycoprotein
- b) Alpha 1-Antitrypsin
- c) Haptoglobin
- d) Immunoglobulin A
- e) Immunoglobulin G
- f) Immunoglobulin M
- g) Transferrin

Assigned Values and Value Assignment Process:

Target value assignment procedure is described in internal SOP and under defined conditions.

Immunoturbidimetric assays are calibrated against an Internal Calibrator Master Lot on a specific automatic analyzer as shown in the table below:

Analyte/assays	Instrument
Alpha 1-Acid Glycoprotein	Roche Hitachi 911
Alpha 1-Antitrypsin	Roche Hitachi 911
Ceruloplasmin	Abbott c8000 ARCHITECT®
Haptoglobin	Roche Hitachi 911
Immunoglobulin A	Roche Hitachi 911
Immunoglobulin G	Roche Hitachi 911
Immunoglobulin M	Roche Hitachi 911
Kappa	Abbott c8000 ARCHITECT®
Lambda	Abbott c8000 ARCHITECT®
Transferrin	Roche Hitachi 911

During each testing run the following samples are tested:

1. Two levels (normal and abnormal) of approved control materials in triplicate to ensure the effectiveness of the measurements.
2. Aliquots of Internal Calibrator Master lot in triplicate
3. Aliquots of Plasmaproteins Cal 3x to be tested in triplicate

For each analyte, three (3) analytical runs on at least two (2) different days are performed.

Single run is accepted if:

1. The results of level normal and abnormal approved control materials are within the expected ranges.
2. The % recovery of Internal Calibrator Master Lot is within 97% - 103%.

The mean and Standard Deviation and %CV of the all measurements are calculated. Data is inspected for outliers detection (single data-Mean > 3SD) and for imprecision of the measurements according to predefined criteria.

In case of absence of outliers and of imprecision $\geq 5\%$, the obtained mean is the Target value.

The obtained Target value has to be within the range indicated in the following table:

Analyte	Plasmaproteins 3x (mg/dL)
alpha 1-Acid Glycoprotein	From 176 to 254
Albumin	From 9344 to 14016
Alpha 1-Antitrypsin	From 334 to 454
Ceruloplasmin	From 66 to 124
Haptoglobin	From 272 to 366
Immunoglobulin A	From 478 to 718
Immunoglobulin G	From 2264 to 3396
Immunoglobulin M	From 204 to 3396
Kappa	From 508 to 762
Lambda	From 306 to 458
Transferrin	From 580 to 872

Directions for Use:

Refer to Draft Package Insert and Draft Labelling on Section IV and Section V.

Performance Characteristics:

Please refer to Section III.

Conclusion:

The modified Plasmaproteins Cal 3x is substantially equivalent to the Predicate Device and to the previous Cleared Plasmaproteins Cal 3x as demonstrated by results obtained in the studies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Sentinel CH. SPA
c/o Mr. Fabio Rota
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Milano, Italy 20152

JUN 25 2008

Re: K081533
Trade/Device Name: Sentinel Plasmaproteins Cal 3x
Regulation Number: 21 CFR 862.1150
Regulation Name: Claibrator
Regulatory Class: Class II
Product Code: JIX
Dated: May 30, 2008
Received: June 02, 2008

Dear Mr. Rota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Plasmaproteins Cal 3x

Indications for Use

Clinical Chemistry – The Sentinel Plasmaproteins Cal 3x is a device intended for medical purposes for use in Ceruloplasmin, Kappa light chains, Lambda light chains, Transferrin, Alpha 1-Acid Glycoprotein, Alpha 1-Antitrypsin, Haptoglobin, Immunoglobulin A, Immunoglobulin G and Immunoglobulin M assays, to establish points of reference that are used in the determination of values in the measurement of Ceruloplasmin, Kappa light chains, Lambda light chains, Transferrin, Alpha 1-Acid Glycoprotein, Alpha 1-Antitrypsin, Haptoglobin, Immunoglobulin A, Immunoglobulin G and Immunoglobulin M in human serum and plasma.

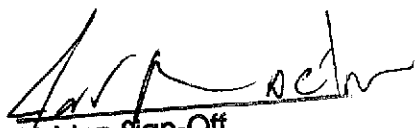
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K08533